REMARKS

Administrative Overview

Claims 24, 26–34, 36–38, 40–44, 46, 47, and 49-52 were pending in this application upon issuance of a final Office action, dated August 25, 2005. The Office action rejects these claims under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6,385,484 to Costa et al. ("**Costa**"). The Office action further rejects claims 24, 26–32, 36–38, 40–42, 46, 47, and 49-52 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,571,118 to Utzinger et al. ("**Utzinger**"), claims 24, 32-34, 38, and 42-44 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,999,844 to Gombrich et al. ("**Gombrich**"), and claims 33, 34, 43, and 44 under 35 U.S.C. § 103(a) as being unpatentable over **Utzinger** in view of **Gombrich**.

Applicants amend claim 38 for clarity. No new matter is added. Following entry of this paper, claims 24, 26–34, 36–38, 40–44, 46, 47, and 49-52 will still be pending.

Applicants Submit Terminal Disclaimer to Overcome Obviousness-Type Double Patenting Rejection

Submitted herewith is a terminal disclaimer executed by the assignee, in compliance with 37 CFR 3.73(b). Applicants respectfully contend this overcomes the obviousness-type double patenting rejection of the pending claims, and Applicants request that the rejection be withdrawn.

Claims Are Patentable Over the Cited Art

Applicants assert that none of the cited references, alone or in combination, teach or suggest the combined elements of either of independent claims 24 or 38, and, therefore, that claims 24 and 38 are patentable in light of the art. Likewise, because a dependent claim includes all the limitations of the independent claim from which it depends, Applicants assert that all pending dependent claims are patentable in light of the art.

The Office action alleges the following in its rejection of independent claims 24 and 38 under 35 U.S.C. § 102(e) in view of **Utzinger**:

> In reference to the use of monochromatic radiation, Utzinger et al. teach the use of monochromatic excitation (col. 8 lines 10-13 lines 22-25 lines 61-67) to determine whether the specimen has a known condition by using fluorescence data and if it is indeterminate, using reflectance data to classify the test specimen.

The cited passages of **Utzinger** are reproduced below as follows:

> The components are: (a) an excitation source 20, which may include an arc lamp 22 and a monochromator 24 for

> monochromatic and broad band excitation, (b) a fiber optic probe 30, which may …
>
> The light source 22 for Fast EEM system 10, which may provide both quasi-monochromatic excitation for fluorescence and broad band illumination for reflectance, may be, in one embodiment, a 150 W ozone free Xe arc lamp (Spectral Energy Corp., Westwood N.J.) with a spherical rear reflector.
>
> In another embodiment, the light source 22 for Fast EEM system 10, which may provide both quasi-monochromatic excitation for fluorescence and broad band illumination for reflectance, may be an ozone-free 450 W Xe arc lamp (FL-1007, Instruments SA, Edison, N.J.). Light used for monochromatic fluorescence excitation may be focused with a spherical mirror (not shown) onto the …

Applicants contend that none of these passages describe the method, taught in the present application, of determining whether fluorescence spectral data from a specimen illuminated with substantially monochromatic radiation is <u>determinate of the test specimen having a first known condition</u>, and, <u>if it is not determinate</u>, classifying the test specimen based at least in part on reflectance spectral data, as recited in claims 24 and 38.

The above passages of **Utzinger** describe a system that may provide monochromatic excitation for fluorescence and broad band illumination for reflectance, but these passages of **Utzinger** do not address the <u>use</u> of data that is obtained, as do claims 24 and 38 of the present application. Elsewhere in **Utzinger**, methods of using data are, in fact, described, but the methods described do not teach or suggest the method of claim 24 or the system of claim 38.

For example, at col. 16 line 40 to col. 70 line 6, **Utzinger** describes various statistical analyses of fluorescence spectral data and reflectance data, but the methods presented appear only to provide class discrimination using fluorescence data obtained with illumination at <u>multiple</u> excitation wavelengths (where reflectance data is not used at all), or using a combination of fluorescence data with reflectance data, where the fluorescence data and reflectance data are <u>combined together</u> in a statistical algorithm.

None of the methods in **Utzinger** discloses screening a specimen for a given condition using only fluorescence spectral data with illumination at one excitation wavelength, <u>and, if the result is not determinate</u>, using reflectance spectral data (either alone or with other data) to classify the specimen.

The present application describes such a method, for example, at page 11, lines 14-22, reproduced as follows:

> At step 320 [of FIG. 3], the computer 202 determines whether the test specimen can be classified as "normal," or "metaplasia," or

> can not be classified by fluorescence spectroscopy alone. This process is described in detail at step 665 of FIG. 6 below. As indicated in step 325, a decision is taken as to whether the test specimen has a definitive state of health, for example that the specimen is "normal." If the test specimen can be classified, for example as normal, the method ends at step 330. In the event that a definitive condition or state of health cannot be ascribed to a test specimen, the computer 202 further analyses information available from a reflectance spectrum or from a plurality of reflectance spectra taken from the test specimen.

It appears the nearest **Utzinger** comes to such a method is described in Example 3 at col. 61 line 62 to col. 62, line 6, and col. 62 lines 23-35, reproduced as follows:

> In our previous analyses, we identified a combination of emission spectra at three excitation wavelength[s] as optimal for diagnosis based on fluorescence spectroscopy and four types of reflectance data which were optimal for diagnosis. We evaluated the performance of the following combinations of data at ESLs of 65%, 75%, 85%, 95%, and 99%: (a) Fluorescence at three excitation wavelengths + each type of reflectance data, (b) Fluorescence at all combinations of two excitation wavelengths + each type of reflectance data, and (c) Fluorescence at each single excitation wavelength + each type of reflectance data.
>
> The performance of the fluorescence algorithm based on three excitation wavelengths does not improve when any of the four types of reflectance data are also incorporated. The performance of fluorescence algorithms based on two excitation wavelengths was lower than that for three excitation wavelengths; incorporation of any of the four types of reflectance spectra did not improve performance. The performance of fluorescence algorithms based on a single excitation wavelength was lower than that for two and three excitation wavelengths. Best results were obtained using spectra at 400 nm excitation. Incorporation of any of the four types of reflectance spectra did not improve performance.

These methods are all different from the method of claim 24 (and the system of claim 38), for example, because they do not perform <u>both</u> of two separate steps: (1) determine whether fluorescence data (using a single excitation wavelength) is determinate of a first known condition, and, if not, (2) classify the specimen based at least in part on reflectance spectral data. Furthermore, the methods of **Utzinger** appear to <u>teach away</u> from the use of fluorescence data obtained at a single excitation wavelength ("[t]he performance of fluorescence algorithms based on a single excitation wavelength was lower than that for two and three excitation wavelengths" at col. 62, lines 29-32). The methods of **Utzinger** even appear to teach away from the use of reflectance data in combination with fluorescence data ("incorporation of any of the four types of

reflectance spectra did not improve performance" at col. 62, lines 25, 28-29, and 34-35). Even though **Utzinger** describes use of an algorithm with both fluorescence and reflectance data, nowhere in **Utzinger** is it suggested to use fluorescence to screen the sample for a given condition, and, if classification is indeterminate, use reflectance data (either alone or in combination with other data) to classify the specimen, as recited in claims 24 and 38.

At col. 25 line 27 to col. 48, line 35, at "Example 2", **Utzinger** presents a composite algorithm to discriminate between more than two tissue types. However, this composite algorithm does not use reflectance data, nor is the use of reflectance data suggested.

The Office action also alleges the following in its rejection of independent claims 24 and 38 under 35 U.S.C. § 102(e) in view of **Utzinger**:

> Regarding claims 24, 32, 38, 42, and 44, Utzinger et al. disclose a method and system of determining a condition of a cervical tissue by obtaining optical information by using a data collection module to obtain reflectance spectral data from a cervical tissue and a computation module to determine whether fluorescence spectral data from said cervical tissue is definitive of said cervical tissue having a known condition, obtaining and processing reflectance spectral data of said tissue using reference reflectance spectral data from a plurality of reference specimens having said condition, and determining said condition of said cervical tissue based on processing and optical information (abstract, col. 2 lines 24-39, col. 3 lines 48-59, col. 4 lines 7-32 lines 57-63, col. 23 lines 4-8, col. 25 lines 56-67, col. 26 lines 20-67, col. 31 lines 49-67, col. 32 lines 1-20).

None of the additionally-cited portions of **Utzinger** address determining whether fluorescence spectral data from a specimen illuminated with substantially monochromatic radiation is determinate of the test specimen having a first known condition, and, if it is not determinate, classifying the test specimen based at least in part on reflectance spectral data, as recited in claims 24 and 38 of the present application.

The Office action alleges the following in its rejection of independent claims 24 and 38 under 35 U.S.C. § 102(e) in view of **Gombrich**:

> Gombrich et al. also teach the use of single excitation wavelength (col. 4 line 26-30).

The cited passage in **Gombrich** is reproduced below as follows:

> The light emitted by light source 40, 50 may encompass a continuum of wavelengths within the ultraviolet, visible and near infrared spectral regions or one or more wavelengths or groups of wavelengths within one or more of these regions.

Applicants respectfully contend this passage does not address the use of data that is obtained from a specimen, as do claims 24 and 38 of the present application.

The Office action also alleges that col. 3 lines 59-67, col. 4 lines 1-22 and 59-67, col. 5, col. 6 lines 62-67, col. 7 lines 1-15, and col. 8 lines 20-67 of **Gombrich** disclose the method of claim 24 and the system of claim 38. The Applicants respectfully disagree.

With regard to use of fluorescence data, **Gombrich** teaches away from classification using fluorescence data obtained at a single wavelength. For example, at col. 5, lines 54-62 of **Gombrich** reads as follows:

> In a preferred embodiment, the system 10 utilizes information obtained at a multiplicity of emission wavelengths generated at a multiplicity of excitation wavelengths, each wavelength combination selected to, in and of itself, to maximize discriminatory power between normal and abnormal tissues. Therefore, instead of relying upon a single measurement to obtain the desired differentiation, system 10 utilizes multiple independent measurements that are combined to obtain substantially improved discrimination.

Gombrich describes reflectance at col. 6, lines 14-17 as follows:

> In another preferred embodiment, reflectance spectrometry provides yet another means of probing tissue status as changes in the tissue status are often evidenced by the changes in colored constituents of the tissue.

The use of reflectance data in **Gombrich** appears to be presented as an alternative ("yet another means") to fluorescence spectroscopy, not something to be used in concert with fluorescence spectroscopy. However, even if it could be considered that **Gombrich** taught the combined use of fluorescence and reflectance data, **Gombrich** does not teach or suggest determining whether fluorescence spectral data from a specimen illuminated with substantially monochromatic radiation is determinate of the test specimen having a first known condition, and, if it is not determinate, classifying the test specimen based at least in part on reflectance spectral data, as recited in claims 24 and 38 of the present application.

Applicants assert that none of the cited references, alone or in combination, teach or suggest the combined elements of either of independent claims 24 or 38, and, therefore, that claims 24 and 38 are patentable in light of the art. Likewise, because a dependent claim includes all the limitations of the independent claim from which it depends, Applicants assert that all pending dependent claims are patentable in light of the art.

Conclusion

Applicants request that the Examiner reconsider the claims in light of the foregoing Response. Applicants respectfully submit that in view of the remarks herein, claims 24, 26–34, 36–38, 40–44, 46, 47, and 49-52 are in condition for allowance. Applicants, therefore, respectfully request issuance of a Notice of Allowance in due course.

If the Examiner believes that it would be helpful to discuss any aspect of the application by telephone, the undersigned representative cordially invites the Examiner to call at the telephone number given below.

Respectfully submitted,

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